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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ACROTECH BIOPHARMA LLC. and CYDEX PHARMACEUTICALS, INC.,	)	
Plaintiffs,	)	
v.	)	
	)	C.A. No. _____
ALEMBIC GLOBAL HOLDING SA, ALEMBIC PHARMACEUTICALS, LTD. and ALEMBIC PHARMACEUTICALS, INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Acrotech Biopharma LLC ("Acrotech") and CyDex Pharmaceuticals, Inc. ("CyDex"), by their undersigned attorneys, for its Complaint against Defendants Alembic Pharmaceuticals, Ltd. ("APL"), Alembic Global Holding SA ("Alembic Global"), and Alembic Pharmaceuticals, Inc. ("Alembic Inc."), (collectively, "Alembic" or "Defendants"), hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the Food and Drug Laws and Patent Laws of the United States, Titles 21 and 35 of the United States Code, respectively, arising from Defendants' submission of Abbreviated New Drug Application No. 212810 (the "Alembic ANDA") to the United States Food and Drug Administration ("FDA") seeking approval to market a generic version of Acrotech's EVOMELA® (Captisol®-enabled Melphalan HCl) for Injection, 50 mg/vial prior to the expiration of United States Patent No. 10,864,183.

THE PARTIES

2. Acrotech is a Delaware limited liability company having its principal place of business at 279 Princeton Hightstown Rd., East Windsor, NJ 08520.

3. CyDex is a Delaware corporation having its principal place of business at 3911 Sorrento Valley Boulevard, Suite 110, San Diego, CA 92121.

4. On information and belief, APL is a corporation organized and existing under the laws of India, having a principal place of business at Alembic Road, Vadodara 390003, Gujarat, India.

5. On information and belief, Alembic Global is a corporation organized and existing under the laws of Switzerland, having a principal place of business at Rue Fritz-Courvoisier 40,

2300 La Chaux-de-Fonds, Switzerland. On information and belief, Alembic Global is a wholly-owned subsidiary of APL and operates under the control and direction of APL.

6. On information and belief, Alembic Inc. is a Delaware corporation having a principal place of business at 750 Route 202, Bridgewater, New Jersey 08807.

7. On information and belief, Alembic Inc. is registered to do business in the State of New Jersey under entity ID # 0101031141, and is registered as a Drug & Medical Device Manufacturer and Wholesaler by the New Jersey Department of Health.

8. On information and belief, Alembic Inc. is a wholly-owned subsidiary of Alembic Global and operates under the control and direction of Alembic Global and APL.

9. On information and belief, APL is in the business of, among other things, developing, preparing, manufacturing, selling, marketing, and distributing generic drugs, including distributing, selling, and marketing generic drugs throughout the United States, including within the State of New Jersey through its own actions and through the actions of its agents and subsidiaries, including Alembic Global and Alembic Inc., from which APL derives a substantial portion of its revenue.

10. On information and belief, APL acted in concert with Alembic Global and Alembic Inc. to prepare and submit the Alembic ANDA for Melphalan hydrochloride for injection (the "Alembic ANDA Product"), which was done at the direction of, under the control of, and for the direct benefit of APL. Following FDA approval of the Alembic ANDA, APL will manufacture and supply the approved generic product to Alembic Global and/or Alembic Inc., which will then market and sell the product throughout the United States at the direction, under the control, and for the direct benefit of APL.

PERSONAL JURISDICTION OVER APL

11. Plaintiffs reallege all preceding paragraphs as if fully set forth herein.

12. On information and belief, APL develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

13. This Court has personal jurisdiction over APL because, inter alia, APL, on information and belief: (1) intends to market, sell or distribute the Alembic ANDA Product to residents of this state; (2) controls Defendant Alembic Inc.; (3) operates through its indirect wholly owned subsidiary Alembic Inc., which maintains a principal place of business in New Jersey; (4) makes its generic drug product available in this State; (5) maintains a broad distributorship network within this State; and (6) enjoys substantial income from sales of its generic pharmaceutical products in this State.

14. Furthermore, this Court has personal jurisdiction over APL because, on information and belief, APL has participated in the preparation and/or submission of ANDA No. 212810 within this jurisdiction.

15. On information and belief, APL has consented to this Court's jurisdiction and initiated litigation in this Judicial district in, at least, *Alembic Pharmaceuticals, Ltd. v. Novartis Pharmaceuticals Corporation*, 2:19-cv-20890-SRC-CLW-SRC.

16. Alternatively, to the extent the above facts do not establish personal jurisdiction over APL, this Court may exercise jurisdiction over APL pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) APL would be a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) APL has sufficient contacts with the United States as a whole, including, but not limited to, manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over APL satisfies due process.

PERSONAL JURISDICTION OVER ALEMBIC GLOBAL

17. Plaintiffs reallege all preceding paragraphs as if fully set forth herein.

18. On information and belief, Alembic Global develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

19. This Court has personal jurisdiction over Alembic Global because, inter alia, APL, on information and belief: (1) intends to market, sell or distribute the Alembic ANDA Product to residents of this state; (2) controls Defendant Alembic Inc.; (3) operates through its wholly owned subsidiary Alembic Inc., which maintains a principal place of business in New Jersey; (4) makes its generic drug product available in this State; (5) maintains a broad distributorship network within this State; and (6) enjoys substantial income from sales of its generic pharmaceutical products in this State.

20. Furthermore, this Court has personal jurisdiction over Alembic Global because, on information and belief, Alembic Global has participated in the preparation and/or submission of ANDA No. 212810 within this jurisdiction.

21. Alternatively, to the extent the above facts do not establish personal jurisdiction over Alembic Global, this Court may exercise jurisdiction over Alembic Global pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Alembic Global would be a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) Alembic Global has sufficient contacts with the United States as a whole, including, but not limited to, manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Alembic Global satisfies due process.

PERSONAL JURISDICTION OVER ALEMBIC INC.

22. Plaintiffs reallege all preceding paragraphs as if fully set forth herein.

23. On information and belief, Alembic Inc. develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

24. This Court has personal jurisdiction over Defendant Alembic Inc. because, inter alia, Alembic Inc., on information and belief: (1) has substantial, continuous, and systematic contacts with this State; (2) intends to market, sell, and/or distribute Alembic's ANDA Products to residents of this State; (3) maintains a principal place of business in this State; (4) is registered to do business in this State; (5) is registered as a Drug and Medical Device Manufacturer and Wholesaler in this State; (6) maintains a broad distributorship network within this State; and (7) enjoys substantial income from sales of its generic pharmaceutical products in this State.

25. Additionally, on information and belief, Alembic Inc. has previously consented to this Court's jurisdiction and has availed itself of the protections afforded by the Court by asserting counterclaims against plaintiffs in this judicial district. *See, e.g., Duke University et al., v. Alembic Pharm. Ltd. et al.*, No. 17-07453 (BRM) (TJB); *Otsuka Pharm. Co., Ltd. v. Alembic Pharm. Ltd. et al.*, No. 14-07405 (JBS) (KMW); *Otsuka Pharm. Co., Ltd. v. Alembic Pharm. Ltd. et al.*, No. 14- 02982 (JBS) (KMW)

26. On information and belief, Alembic Inc. has availed itself of the rights and benefits of the State of New Jersey by, among other things, registering to do business in the State of New Jersey under entity ID # 0101031141, and registering as a Drug & Medical Device Manufacturer and Wholesaler with the New Jersey Department of Health.

JURISDICTION AND VENUE

27. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100 et seq., generally, and 35 U.S.C. § 271(e)(2), specifically, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

28. Venue is proper in this Court under 28 U.S.C. §§ 1391 and/or 1400(b).

29. Venue is proper against Alembic Inc. as it is a corporation having a principal place of business at 750 Route 202, Bridgewater, New Jersey 08807 and is furthermore registered to do business in the State of New Jersey. Furthermore, on information and belief, Alembic Inc. acted in concert with APL and Alembic Global and Alembic Inc. in this Judicial District to prepare and submit the Alembic ANDA and, following approval of the Alembic ANDA, will then market and sell the Alembic ANDA Product throughout the United States, including in this Judicial District.

30. Venue is proper against APL as it is a company existing under the laws of India, having a principal place of business at Alembic Road, Vadodara 390003, Gujarat, India, and is therefore not a resident of the United States. Additionally, as described above, this Court has personal jurisdiction over APL. Furthermore, on information and belief, APL acted in concert with Alembic Global and Alembic Inc. in this Judicial District to prepare and submit the Alembic ANDA, which was done at the direction of, under the control of, and for the direct benefit of APL. Following FDA approval of the Alembic ANDA, APL will manufacture and supply the approved generic product to Alembic Global and/or Alembic Inc., which will then market and sell the product throughout the United States, including in this Judicial District, at the direction, under the control, and for the direct benefit of APL.

31. Venue is proper against Alembic Global as it is a corporation existing under the laws Switzerland, having a principal place of business at Rue Fritz-Courvoisier 40, 2300 La

Chaux-de-Fonds, Switzerland, and is therefore not a resident of the United States. Additionally, as described above, this Court has personal jurisdiction over Alembic Global.

THE PATENTS-IN-SUIT

32. On December 15, 2020, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued United States Patent No. 10,864,183 ("the '183 patent"), entitled "Injectable Nitrogen Mustard Compositions Comprising a Cyclodextrin Derivative and Methods of Making and Using the Same" A true and correct copy of the '183 patent is attached hereto as Exhibit A.

33. The '183 patent is assigned to CyDex. Acrotech is an exclusive licensee of the '183 patent.

EVOMELA®

34. Acrotech is the holder of New Drug Application ("NDA") No. 207155 for Captisol®-enabled Melphalan HCl for Injection; 50mg (free base)/vial, which is sold under the trade name EVOMELA®.

35. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '183 patent has been submitted for listing in the FDA publication entitled *Approved Drug Products and Therapeutic Equivalence Evaluations* ("the Orange Book") in connection with NDA No. 207155 as covering EVOMELA®.

COUNT I - INFRINGEMENT OF THE '183 PATENT

36. Plaintiffs reallege all preceding paragraphs as if fully set forth herein.

37. On information and belief, Alembic submitted the Alembic ANDA to the FDA, pursuant to 21 U.S.C. § 355(j) seeking approval to market the Alembic ANDA Product.

38. The Alembic ANDA refers to and relies upon the EVOMELA® NDA and contains data that, according to Alembic, demonstrates the bioequivalence of the Alembic ANDA Product to EVOMELA®.

39. On information and belief, the Alembic ANDA contains a certification, pursuant to 21 U.S.C. § 355(J)(2)(A)(vii)(IV) ("Paragraph IV Certification"), that inter alia, certain claims of U.S. Patent Nos. 8,410,077 (the "'077 patent"); 9,200,088 (the "'088 patent"); 9,493,582 (the "'582 patent"), which are listed in the Orange Book as covering EVOMELA® will not be infringed by the commercial manufacture, use, or sale of the Alembic ANDA Product and, before approval, will contain a Paragraph IV Certification that, inter alia, certain claims of the '183 patent will not be infringed by the commercial manufacture, use, or sale of the Alembic AND Product.

40. CyDex sued Alembic for infringement of the '077, '088, and '582 patents in *CyDex Pharmaceuticals, Inc., v. Alembic Global Holding SA*, 19-cv-956 (LPS)(JLH). The suit remains pending in the United States District Court for the District of Delaware.

41. Alembic has infringed at least one claim of the '183 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Alembic ANDA, by which Alembic seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Alembic ANDA Product prior to the expiration of the '183 patent.

42. Alembic has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Alembic ANDA Product in the event the FDA approves the Alembic ANDA. Accordingly, an actual and immediate controversy exists regarding Alembic's infringement of the '183 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

43. Alembic's commercial manufacture, use, offer to sell, or sale of the Alembic ANDA Product within the United States, or importation of the Alembic ANDA Product into the

United States, during the term of the '183 patent would infringe the '183 patent under 35 U.S.C. § 271(a), (b), (c), (f) and/or (g).

44. On information and belief, the Alembic ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe the '183 patent.

45. On information and belief, the use of the Alembic ANDA Product constitutes a material part of the claims of the '183 patent; Alembic knows that its ANDA Product is especially made or adapted for use in infringing the claims of the '183 patent; and its ANDA Product is not staple articles of commerce or commodity of commerce suitable for substantial noninfringing use.

46. On information and belief, the offering to sell, sale, and/or importation of the Alembic ANDA Product would contributorily infringe the claims of the '183 patent.

47. On information and belief, Alembic had knowledge of the '183 patent and, by its promotional activities and package inserts for its ANDA Product, knows or should know that it will aid and abet another's direct infringement of the claims of the '183 patent.

48. On information and belief, the offering to sell, sale, and/or importation of the Alembic ANDA Product would actively induce infringement of the claims of the '183 patent.

49. Plaintiffs will be substantially and irreparably harmed if Alembic is not enjoined from infringing the '183 patent.

50. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Plaintiffs' reasonable attorney fees.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court enter judgment against Defendants and for the following relief:

a. A Judgment be entered that Alembic has infringed at least one claim of the '183 patent by submitting the Alembic ANDA;

b. That Defendants, their officers, agents, servants, employees, and those persons acting in active concert or participation with all or any of them from be preliminarily and permanently enjoined from: (i) engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of drugs or drugs for use in methods of administering drugs claimed in the '183 patent, and (ii) seeking, obtaining or maintaining approval of the Alembic ANDA until the expiration of the '183 patent or such other later time as the Court may determine;

c. A judgment ordering that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the Alembic ANDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the latest of the expiration dates of the '183 patent, including any extensions;

d. That Plaintiffs be awarded monetary relief if Defendants commercially use, offer to sell, or sell their respective proposed generic versions of EVOMELA® or any other product that infringes or induces or contributes to the infringement of the '183 patent, within the United States, prior to the expiration of that patent, including any extensions, and that any such monetary relief be awarded to Plaintiffs with prejudgment interest;

e. Costs and expenses in this action; and

f. Such other and further relief as the Court deems just and appropriate.

Dated: December 15, 2020

Respectfully submitted

/s/ Rebekah Conroy
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